VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 11/14/06

Board Members:

James Gray, M.D., Chair
Frank Landry, M.D.
Richard Harvie, R. Ph.
Norm Ward, M.D.
Michael Scovner, M.D.
Andrew Miller, R. Ph.
Tim Thompson, M.D.

Staff:

Ann Rugg, OVHA
Jennifer Mullikin, OVHA
Robin Farnsworth, OVHA
Scott Strenio, M.D., OVHA
Diane Neal, R.Ph., MHP
Natalie Santamore, OVHA
Ann Bennett, OVHA
David Calabrese, R.Ph., MHP

Guests:

Andrew Tenaglia, Berlex
Betsy Perez, Green Mountain Urology
Bill Eicholzier, Sanofi-Aventis
Bob Clark, Novartis
Carl Marchand, AstraZeneca
Carl Peppe, GSK
Carl Possidente, Pfizer
Christine Tynun, BIPI
Claudio Faria, ScheringPlough
Curtis Williams, AstraZeneca
Gress Denton, NovoNordisk
Jenifer Buttle, Merck
Jim Pfohl, P&GP
Jody Lesko, BIPI
Julee Guimipers, BIPI
Kevin Boehmcke, Abbott
Kevin Farrell, Abbott
Kirk Dzenko, Boehringer-Ingelheim
Leslie Mason, Alcon
Lisa Wentworth, Merck-Schering-Plough
Lyndon Braun, Santarus
Mark Kaplan, Abbott
Mary Kaysen, Takeda
Matt Badalucco, Merck
Matthew Sasso, Sanofi-Aventis
Michael Zdrojewski, ScheringPlough
Mike Day, Ferndale Labs
Mike Parrillo, Ferndale Labs
Mike Tulumello, Sanofi-Aventis
Paul Fauikos, BIPI
Peter Mittelstadt, Pfizer
Ron Poppel, BMS
Sam Davis, BMS
Tom Martin, Boehringer-Ingelheim

James Gray, M.D., Chair called the meeting to order at 7:12 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The October 2006 meeting minutes were accepted as printed without amendment.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Dr. Gray's Retirement from DUR Board: It was announced that this was Dr. Gray's last meeting. Dr. Gray was thanked for his 10 years of service to the Vermont Medicaid DUR Board and his tenure as chair. A plaque of appreciation was presented to Dr. Gray as he retires.
- Part D Recovery: To date, CMS has been billed 6 million dollars for pharmacy benefits provided by OVHA during the transition to Part D. Notice has been received from CMS of an approved payment of 5 million dollars. In addition, 1 million dollars in administrative costs has been billed and approved. An outstanding 6 million dollars will attempt to be recovered through the Part D plans on a claim by claim basis.

4. Medical Director Update: *Scott Strenio, M.D. - Medical Director, OVHA*

- Care Coordination: Care Coordinators have been hired for Washington, Caledonia and Chittenden counties. These Care Coordinators will focus on the most complex, high expense patients.
- Buprenorphine: Dr. Strenio discussed reimbursement of physicians who are willing to provide care for opiate dependent patients. In addition, the Department of Corrections has an initiative scheduled to be rolled out before the end of the year that will start individuals on buprenorphine before their release from prison in an effort to reduce the rate of recidivism.
- Chronic Care Management Plan: An RFP has gone out to invite submissions for chronic care management proposals.
- Vaccines: Dr. Strenio summarized an email received from a physician representing the Medical Society regarding reimbursement of physicians for vaccines, which is felt to be inadequate. There was also discussion around the difficulty in being able to obtain vaccines routinely.
- Insulins on the PDL: Dr. Strenio distributed an email to board members received from Dr. Muriel Nathan regarding insulins on the PDL. The contents of the email will be discussed at a later board meeting.
- Patients with Asthma/Controller Medications: Dr. Strenio noted that Dr. Michael Scovner had sent him some suggestions regarding the DUR board initiatives to increase the use of controller medications in patients with asthma who receive short and long-acting beta-agonist inhalers. This strategy will be discussed at a later board meeting.

5. Follow-up items from Previous Meeting

- No follow-up items

6. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, MHP*

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Growth Stimulating Agents: The revised clinical criteria were presented. The criteria were updated with FDA approved indications. Clarification was also added to clearly define when confirmation of non-closure of the epiphyseal plates was needed.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Antihyperkinesis Medications: The revised clinical criteria were presented. The criteria were revised due to requests for use of Provigil® (modafanil) for the indication of ADHD in children. There was discussion concerning the FDA non-approvable letter sent to the company developing Sparlon® (modafanil) for this same indication. The FDA ruled that modafanil was not acceptably safe for use in children for treatment of ADHD due to a suspected case of Steven's-Johnson syndrome during a clinical trial.

Public Comment: No public comment.

Board Decision: The Board approved the clinical criteria with the further revision to prohibit the use of Provigil® for treatment of ADHD in children 12 years old and under .

- Coronary Vasodilators/Antianginals including Ranexa® (ranolazine): The revised clinical criteria updated to include the criteria for Ranexa® as voted upon at the October DUR board meeting were presented. Coverage would require a PA and previous history of at least one prescription from two of the following drug categories in the most recent 180 days (beta-blockers, maintenance nitrates or calcium channel blockers). Coverage would not be approved for patients with hepatic insufficiency, history of or increased risk of QT prolongation and concurrent use of medications that may prolong the QT interval. Quantity limit will be 4 tablets per day.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

7. Clinical Update: New Drug Reviews: *Diane Neal, R.Ph. MHP*

- Deferred until next month due to length of agenda and time constraints.

8. Drug Classes Revisited: *David Calabrese, R.Ph, MHP*

Note: All drug/criteria decisions from this section will be reflected in the **01/01/07** PDL and/or Clinical Criteria update unless specified otherwise.

- Alzheimer's Disease Medications-Cholinesterase Inhibitors - Exelon® (rivastigmine)
  Proposed for move from PDL preferred to non-preferred (PA required) status, existing users to be grandfathered.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Analgesics-Narcotics-Long-Acting - Duragesic® (brand fentanyl patch)
  Proposed for move from PDL preferred to non-preferred (PA required) status, no grandfathering recommended for existing patients as interchangeable generics available on PDL.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Antidepressants-Novel – Wellbutrin-XL® (bupropion-XL)
  Proposed for move from non-preferred (PA required) status to PDL preferred with coverage contingent upon previous trial of at least one generic SSRI.

Public Comment: Carl Peppe, GSK – Commented on the length of the Wellbutrin XL® contract and will seek clarification.

Board Decision: The Board deferred a decision until the next meeting. Further information was requested.

- Antidiabetics-Peptide Hormones – Byetta® (exenatide)
  Proposed for move from non-preferred (PA required) status to PDL preferred. An automated step therapy edit will be employed to validate a previous trial of at least two oral agents.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Anti-Hypertensives-ACEs with CCBs – Tarka® (trandolapril/verapamil)
  Proposed for move from non-preferred (PA required) status to PDL preferred.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Anti-Hypertensives-ARBs, ARB Combinations – Micardis® (telmisartan) and Micardis-HCT® (telmisartan/hydrochlorothiazide)
  Proposed for move from non-preferred (PA required) status to PDL preferred.

Anti-Hypertensives-ARBs, ARB Combinations – Teveten® (eprosartan) and Teveten-HCT® (eprosartan/hydrochlorothiazide)
Proposed for move from PDL preferred to non-preferred (PA required) status, existing users to be grandfathered.

Public Comment: Ron Poppel, BMS – Asked about the SSDC process and inquired why all 3 states didn't accept the same contracts. *David Calabrese, R.Ph, MHP,* explained the process and also that Vermont could not broaden the number of choices in this particular drug category.

Board Decision: The Board approved as recommended.

- Anti-Infectives-Cephalosporins-3rd Generation – Suprax® (cefixime)
  Proposed for move from non-preferred (PA required) status to PDL preferred.
  Anti-Infectives-Macrolides - Zithromax® (brand azithromycin)
  Proposed for move from PDL preferred to non-preferred (PA required) status.
  Anti-Infectives-Quinolones - Avelox® (moxifloxacin)
  Proposed for move from PDL preferred to non-preferred (PA required) status

Public Comment: Claudio Faria, ScheringPlough – Discussed the spectrum of activity of Avelox®.

Board Decision: The Board approved as recommended.

- Anti-Migraine Agents-Triptans – Axert® (almotriptan)
  Proposed for move from non-preferred (PA required) status to PDL preferred.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- BPH Agents-Alpha Blockers – Uroxatral® (alfuzosin)
  Proposed for move from non-preferred (PA required) status to PDL preferred. An automated step therapy edit was proposed for all new starts on either Uroxatral® or Flomax® requiring first line trial of generic terazosin or doxazosin.

Public Comment: Tom Jackson, MD, FAHC Urology (email read by Scott Strenio, MD) – requested that Uroxatral® and Flomax® be available as first line options as they are easier to titrate and there is less problem with orthostatic hypotension. *Betsy Perez, MD, Green Mountain Urology* – agreed that all agents in this category are efficacious but said that it was too difficult and time consuming to monitor blood pressure for patients on generic terazosin and doxazosin. She explained that she rarely has to titrate Flomax® and requested that the step therapy edit proposal not be adopted. *Kirk Dzenko, Boehringer-Ingelheim* – Discussed the uroselectivity of Flomax® and commented that there is no additional orthostatic hypotension experienced by patients when given with other anti-hypertensive medications.

Board Decision: The Board recommended that Uroxatral® be moved to PDL preferred status but voted to not adopt the proposed automated step therapy edit.

- Gastrointestinals – Proton Pump Inhibitors - Prevacid® SOLUTABS (lansoprazole)
  Proposed for move from PDL preferred to non-preferred (PA required) status. Proposed change affects this dosage form only.

Public Comment: Curtis Williams, AstraZeneca – Discussed Nexium® and requested a clinical and financial review for consideration on the 2007 PDL. *Unidentified Speaker(did not sign in), TAP* – Discussed the use of Prevacid® Solutabs in pediatrics and explained that the solutabs dissolve easily in water in an oral syringe and have a strawberry flavor making them a suitable choice for patients 7 years and younger.

Board Decision: The Board approved moving Prevacid® Solutabs to non-preferred but they will remain available for use in patients 7 years and younger without PA.

- Growth Stimulating Agents - Norditropin® and Saizen®
  Proposed for move from PDL preferred to non-preferred (PA required) status, existing users to be grandfathered.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Hepatitis C Agents - Copegus® (brand ribavirin)
  Proposed for move from PDL preferred to non-preferred (PA required) status.
  Hepatitis C Agents – ribvirin (generic)
  Proposed for move from non-preferred (PA required) status to PDL preferred.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Lipotropics-Fibric Acid Derivatives - fenofibrate (generic)
  Proposed for move from PDL preferred to non-preferred (PA required) status.
  Lipotropics-Statins - Zocor® (brand simvastatin) Proposed Effective Date 02/01/07
  Proposed for move from PDL preferred to non-preferred (PA required) status.
  Lipotropics-Statins – simvastatin (generic)
  Proposed for move from non-preferred (PA required) status to PDL preferred

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Multiple Sclerosis Injectables - Avonex® (interferon B-1a)
  Proposed for move from PDL preferred to non-preferred (PA required) status, existing users to be grandfathered.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Ophthalmics-Glaucoma Agents/Miotics – Travatan® (travoprost)
  Proposed for move from non-preferred (PA required) status to PDL preferred with coverage contingent upon same criteria as Lumigan® (previous trial of PDL beta-blocker, alpha-adrenergic or CAI agent).

Public Comment: Leslie Mason, Alcon – Discussed a new product, Travatan Z®, which does not contain benzalkonium chloride (BAK) as a preservative.

Board Decision: The Board voted to move Travatan® to PDL preferred status and asked for pricing information on Travatan Z® before making a decision about its status.

- Ossification Enhancers – Boniva® (ibandronate)
  Proposed for move from non-preferred (PA required) status to PDL preferred.
  Ossification Enhancers – Actonel® (risedronate) and Actonel w/calcium® (risedronate/calcium carbonate)
  Proposed for move from PDL preferred to non-preferred (PA required) status. Active conversion of existing Actonel® and Actonel w/calcium® users to either Boniva® or Fosamax® would be required. A patient specific mailing would be sent out to prescribers of existing users.

Public Comment: Jim Pfohl, Proctor and Gamble - Discussed the use of Actonel® in patients who experience GI intolerability with other products.

Board Decision: The Board approved as recommended but asked that physicians be given until 02/01/07 to complete conversion of their patients who are currently using Actonel® and Actonel w/calcium® to alternative PDL preferred products.

- Parkinson's Treatments – Parcopa® (carbidopa/levodopa MLT)
  Proposed for move from non-preferred (PA required) status to PDL preferred.
  Parkinson's Treatments – Parlodel® (brand), Permax® (brand), Eldepryl® (brand) and Symmetrel® (brand)
  Proposed for move from PDL preferred to non-preferred (PA required) status.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Pulmonary-Antihistamines – 2nd Generation - Allegra® (brand fexofenadine)
  Proposed for move from PDL preferred to non-preferred (PA required) status. Generic fexofenadine remains available on the PDL after loratadine failure.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Pulmonary-Nasal Glucocorticoids – Nasacort AQ® (triamcinolone)
  Proposed for move from non-preferred (PA required) status to PDL preferred.
  Pulmonary-Nasal Glucocorticoids – fluticasone (generic)
  Proposed for move from PDL preferred to non-preferred (PA required) status. Flonase® (brand fluticasone) to remain on PDL preferred list.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

9. RetroDUR: *Diane Neal, R.Ph. MHP*

June/October – Extensive use of a short-acting beta-agonist and no concomitant controller medication: A summary of the RetroDUR results was presented. Faxes were sent to 39 pharmacies for 53 individual patients. Pharmacist response rate was 55 %. Of responses returned, 75 % of pharmacists planned to review medication therapy either with the patient by flagging their profile and speaking to them when they next returned to the pharmacy or by contacting them by phone or with the physician by contacting the physician directly. 14 % of returned responses indicated that the patient was now on a controller medication.

Combined Summary: (Physician Mailing and/or Pharmacist Fax)

Total Patients Targeted: 422
Patient Profiles Reviewed: 422
Patient Profiles selected for mailing letter/faxing letter: 120
Patients who will receive follow-up by physician or pharmacist: 76 = 63 %
Patient Now on Controller Medication (no action needed): 9 = 8 %
Physician/Pharmacist Feels Use Not Excessive: 7 = 6%
Physician Choose Not to Intervene: 4 = 3 %
Patient lost to follow-up or No Responses from Physician/Pharmacist: 24 = 20 %

Public Comment: No public comment.

Board Decision: None required**.**

- July/October – Long-acting beta-agonist use with no controller medication:

A summary of the RetroDUR results was presented. Faxes were sent to 17 pharmacies for 18 individual patients. Pharmacist response rate was 61 %. Of responses returned, 54 % of pharmacists planned to review medication therapy either with the patient by flagging their profile and speaking to them when they next returned to the pharmacy or with the physician by contacting the physician directly. 27 % of returned responses indicated that the patient was now on a controller medication. 18 % of responders indicated that the patient was lost to follow-up either by moving from the area or having been in a drug rehab facility for short term stay.

Combined Summary: (Physician Mailing and/or Pharmacist Fax)

Total Patients Targeted: 128
Patient Profiles Reviewed: 128
Patient Profiles selected for mailing letter/faxing letter: 32
Patients who will receive follow-up by physician or pharmacist: 18 = 56 %
Patient Now on Controller Medication (no action needed): 3 = 9 %
Patient with COPD Diagnosis: 2 = 6%
Patient lost to follow-up or No Responses from Physician/Pharmacist: 9 = 28 %

Public Comment: No public comment.

Board Decision: None required.

- November – Therapy with Multiple Atypical Antipsychotics–
  Proposed mailing to be sent to prescribers included in packet. A response form will also be included as well as a patient specific profile. Results to be discussed at a later board meeting.

Public Comment: No public comment.

Board Decision: Approved as written. The Board requested that the response form include one option that would indicate that the therapy had been initially prescribed by another prescriber.

10. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, MHP*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

11. General Announcements:

- Effexor® and Effexor XR® (venlafaxine HCl) - *Diane Neal, R.Ph, MHP*
  The FDA and Wyeth notification to healthcare professionals of increased risk of fatal outcomes with overdose when combined with alcohol and other drugs was presented.

Public Comment: No public comment.

Board Decision: The Board recommended posting the Effexor® and Effexor XR® "Dear Healthcare Provider Letter" on the OVHA web site.

12. Adjourn: Meeting adjourned at 9:10 p.m.

Next DUR Board Meeting
Tuesday, December 12, 2006
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.